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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,010	02/02/2001	Gregory Bruce Wilson	0179/61248-A/JPW/BJA	7419

7590 07/02/2003

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1185 Avenue of the Americas  
New York, NY 10036

EXAMINER
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LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/02/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/776,010

Applicant(s)

WILSON ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-45 is/are pending in the application.
- 4a) Of the above claim(s) 41, 44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-40 and 42-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Claims 32-45 are pending.

#### ***Election/Restrictions***

1. Applicant's election with traverse of Group III, claims 40, 42 and 43 in Paper No. 14 is acknowledged. The traversal is on the ground(s) that claims are not written in an independent form and searching all of the claims would not constitute a serious burden.
2. Applicants' argument has been respectfully considered; claims 32-39 are rejoined with the elected group III. However, claims 41, 44-45 are not rejoined because it is directed to the different method of using the product, which requires different search and exhibit different patentable weight.

Claims 32-40 and 42-43 are considered before the examiner.

Applicants are reminded to cancel the claims 41, 44-45 drawn to the non-elected group.

#### ***RCE***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/08/2002 has been entered. An action on the RCE follows.

#### ***Response to Amendment***

This is a response to the amendment, paper No. 11, filed 10/08/02. Claims 1-9, 12-24 and 28-31 are canceled. New Claims 32-45 are added. Claims 32-45 are pending before the examiner.

Since Applicants canceled all rejected claims and filed a new claims, Office will not address all the issues raised in the previous Office Action.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 40, 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the administering dosage and rout etc.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 32, 38, 40, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (Patent No. 4,816, 563) and Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86).

7. The claimed invention is drawn to a composition and a method for using the composition to treat chronic fatigue syndrome (CFS) patients, wherein the composition comprises a cell free secretion from a mammary gland secretion or a lyophilized product of the cell-free fluid from an animal infected with human herpesvirus-6A and human Herpesvirus-6B

8. Ablashi et al. teach a method for treating patients suffering Chronic Fatigue Syndrome (CFS) with antigen specific transfer factor (TF), which is active against EBV, HHV-6 and CMV. The TF is extracted from spleens of BALB/c mice immunized with EBV, CMV, and HHV-6 live virus. Because the transfer factor can produce activity cross the species, injection of the isolated TF significantly alleviates the clinical symptom of the patients suffering from chronic fatigue syndrome (CFS) caused by HHV6 infection (see entire document). Ablashi et al. Do not teach to use cell free product secreted from a mammal, which contains the antigen specific TF against HSV-6 or HSV-5..

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9. Wilson et al. disclose a method for producing an antigen specific excreted transfer factor (TF) isolated from a colostrums or milk of a bovine, and it can be lyophilized and stored dry for later use and/or reconstituted in sterile pyrogen-free water, physiologic saline or any other fluid suitable for injection or oral administration (lines 26 on col. 5 through line 68 on col. 6). Wilson et al. also teach that the antigen specific TF is used for enhance the cellular immunity against specific antigens to which the TF-producing animal is immunized, such as herpes simplex virus, Newcastle's disease, Marek's disease etc.

10. Therefore, it would have been obvious for a person skill in the art at the time the application was filed to be motivated by Ablashi et al and Wilson et al. to use the TF derived from the milk or clostridium product for treating the CFS because the TF derived from a mammal milk product would be much easier and economic to be accepted by patients or market. Hence the claimed invention as a whole is prima facie obvious absence unexpected results.

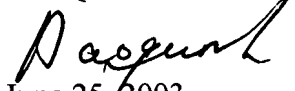
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li



June 25, 2003